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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,514

06/09/2005

Tsuyoshi Naganuma

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,514	Applicant(s) NAGANUMA ET AL.	
	Examiner WALTER E. WEBB	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,9,11,12 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 9, 11, 12 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 3/31/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter Rejection

Claims 1, 8, 9, 11, 12 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite the phrases "a granular material" and "partially pregelatinized starch." Applicant states that support for these amendments to claim 1 can be found in claims 5, 6, 7 and 10, and at page 13 line 8. However, these

cancelled claims nor the specification at page 13 support these amended phrases.

These phrases, therefore, constitute new matter.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 9, 11, 12 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "partially pregelatinized starch" in claim 1 is a relative term which renders the claim indefinite. The term "partially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear to what degree the starch has to be partially pregelatinized to satisfy the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 103

Applicant argues that a person of ordinary skill in the art would not formulate the instant composition based on the broad nature teachings of Ishihara. Applicant argues that the present invention has unexpectedly superior and unpredictable advantages over Ishihara, which is discussed in the affidavit submitted by Tsuyoshi Naganuma. In the affidavit, Naganuma describes a test performed comparing a formulation of the

instant invention with that of a formulation from Ishihara. Naganuma discusses how, the formulation of the instant invention has a higher dissolution than that of the formulation from Ishihara. The affidavit also discussed filling problems during encapsulation with the Ishihara example.

However, applicant's data shown by affidavit and the newly amended claims include limitations that were not considered in the previous action, e.g. partially pregelatinized starch. This limitation is also not taught by the prior art references. Accordingly, applicant's arguments are moot, and a new ground of rejection has been made below.

New Rejection Necessitated by Applicant's Amendment

Claims 1, 8, 9, 11, 12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitazawa et al., (previous) in view of Ishihara et al., (previous) and in further view of Salpekar et al., (US 4,757,090) and Shah (US 5,370,878).

Kitazawa et al., and Ishihara et al., (taught previously), differs from the instant claims insofar as it does not teach a capsule comprising partially pregelatinized starch wherein 85% dissolution time is not more than 60 minutes.

Salpekar et al. teach a composition of acetaminophen useful in direct tableting process, where pregelatinized starch is included in an amount effective for imparting to the composition a short dissolution time, e.g. about 20 minutes or less for 80% or more of active the active compound to dissolve. (See abstract, and col. 2, lines 60-66.) They teach adding lubricants such as sodium lauryl sulfate, magnesium stearate at 0.10 to

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about 1 percent based on the dry weight of the composition. (See col. 3, lines 13-23.)

These amounts are such that disintegration, dissolution time will not be increased. (See col. 3, lines 5-10.) Salpekar does not teach a compound formula of claim 1.

Shah also teaches a composition with short dissolution time, but suggests using either partially or completely pregelatinized starch. (See col. 3, lines 56-64.) Shah does not teach a compound formula of claim 1.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to formulate the capsule of Kitazawa to include D-mannitol, partially pregelatinized starch, sodium lauryl sulfate and a lubricant such as magnesium stearate. Ishihara et al, provides motivation for combining D-mannitol, pregelatinized starch (see [620]), sodium lauryl sulfate, magnesium stearate, and a light shielding capsule with titanium oxide with the formula of claim 1. However, Ishihara does not provide motivation for adding partially pregelatinized starch. Salpekar provides motivation for specifically adding pregelatinized starch, since it decreases dissolution time to about 20 minutes or less where 80% or more the active compound is dissolved. Shah provides that pregelatinized and partially pregelatinized starch are both available for use in a composition with low dissolution time. The artisan would therefore have a reasonable expectation of similar success using partially pregelatinized starch and pregelatinized starch. Salpekar also provides motivation for using equal parts of magnesium stearate and sodium lauryl sulfate, e.g. 1%, which meets the limitations of claims 9 and 27.

Based on these teachings of the prior art, the results obtained in the declaration would have been expected, i.e. the artisan would have expected a short dissolution time not more than 60 minutes wherein 85% of the active compound is dissolved when pregelatinized or partially pregelatinized starch is made part of the composition.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612